

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

ASTRAZENECA AB and ASTRAZENECA
PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and
KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No. 1:18-cv-00193-IMK

ASTRAZENECA AB and ASTRAZENECA
PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and
KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No. 1:19-cv-00203-IMK

STIPULATION AND ORDER

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively “Plaintiffs”) and Defendants Mylan Pharmaceuticals Inc., and Kindeva Drug Delivery L.P. (collectively “Defendants”), based on the Court’s Order dated March 22, 2022 (Dkt. No. 521), to narrow the issues in dispute for purposes of trial, hereby agree and stipulate to the following:

WHEREAS, Plaintiffs filed this action for infringement of U.S. Patent Nos. 7,759,328 (“’328 patent”); 8,143,239 (“’239 patent”); 8,575,137 (“’137 patent”) (collectively the “Federal Circuit Patents”); and 10,166,247 (“’247 patent”) (together with the Federal Circuit Patents, the “patents-in-suit”) in connection with Defendants’ Abbreviated New Drug Application, ANDA No. 211699, to the U.S. Food and Drug Administration for a generic version of Symbicort® inhalation products (“Defendants’ ANDA Products”);

WHEREAS, Plaintiffs asserted infringement of specific claims of the patents-in-suit, specifically, claims 1, 4, 5, 7, 9, 10, 13 and 14 of the ’328 patent (“the ’328 Asserted Claims”); claims 1-6, 8-10, 12, 13, 16, 18-21, 24 and 26-29 of the ’239 patent (“the ’239 Asserted Claims”); claims 1-6, 9, 10 and 13-53 of the ’137 patent (“the ’137 Asserted Claims”); and claims 1-7 and 10-12 of the ’247 patent (“the ’247 Asserted Claims”);

WHEREAS, Defendants stipulated to judgment of infringement of the ’328 Asserted Claims, ’239 Asserted Claims, and ’137 Asserted Claims, to the extent they were asserted by Plaintiffs at trial and found to be valid and enforceable (Dkt. No. 349), under this Court’s construction of the term “0.001%,” set forth in the Court’s Memorandum and Order dated August 12, 2020 (Dkt. No. 317), and subject to Defendants’ appeal; and Plaintiffs stipulated to dismissal of the ’247 Asserted Claims, subject to vacatur if the Court’s construction of the term “0.001%” was reversed or modified by the Federal Circuit;

WHEREAS, Plaintiffs asserted at trial a subset of the Asserted Claims, specifically, claims 9, 10, 13, and 14 of the '328 patent; claims 12, 13, 18, and 19 of the '239 patent; and claims 10 and 19 of the '137 patent (collectively, the “Federal Circuit Claims”) (Dkt. No. 390);

WHEREAS, the parties proceeded to trial on obviousness of the Federal Circuit Claims, and the Court concluded that Defendants failed to prove obviousness of any claim (Dkt. No. 431);

WHEREAS, Defendants appealed from the stipulated judgment of infringement and the Court’s judgment of nonobviousness;

WHEREAS, on December 8, 2021, the Federal Circuit Court of Appeals issued a decision affirming the Court’s judgment of nonobviousness of the Federal Circuit Claims, adopting Defendants’ proposed construction of the term “0.001%,” construing the term “0.001%” as that precise number, with only minor variations, i.e., 0.00095% to 0.00104% (the “Federal Circuit Claim Construction”), vacating the stipulated judgment of infringement, and remanding for further proceedings;

WHEREAS, on March 22, 2022, the Court vacated (Dkt. No. 512) the parties’ earlier infringement stipulation (Dkt. No. 349);

WHEREAS, Defendants moved to strike Dr. Cory Berkland’s expert report dated July 24, 2020, and expert declaration dated March 7, 2022 (Dkt. No. 508), and Plaintiffs opposed (Dkt. No. 511);

WHEREAS, on March 22, 2022, the Court granted Defendants’ motion to strike (Dkt. No. 521) (“Strike Order”); and

WHEREAS, the parties have met and conferred to narrow the issues for trial.

NOW THEREFORE, the parties stipulate and agree as follows:

1. Plaintiffs consent to the entry of judgment in this action that the filing of ANDA No. 211699 does not infringe the Federal Circuit Patents or claim 4 of the '247 patent, literally or under the doctrine of equivalents, based on the Federal Circuit Claim Construction, and all claims and counterclaims related to the Federal Circuit Patents and claim 4 of the '247 patent are therefore DISMISSED WITH PREJUDICE.

2. Notwithstanding paragraph 1, if the U.S. Court of Appeals for the Federal Circuit reverses or modifies the Court's Strike Order such that the Strike Order is vacated or reversed, then Plaintiffs may request, and Defendants will not contest, vacatur of this stipulation of dismissal of the Federal Circuit Patents and claim 4 of the '247 patent. If this stipulated order is dismissed or vacated, Plaintiffs reserve all rights to assert the Federal Circuit Claims or infringement of claim 4 of the '247 patent, if valid, and Defendants likewise reserve all rights, defenses and counterclaims to the assertion of any Federal Circuit Claims and claim 4 of the '247 patent.

3. Defendants consent to the entry of judgment in this action that the submission of ANDA No. 211699 infringes, and Defendants' ANDA Products would infringe, claims 1-3, 5-7, and 10-12 of the '247 patent, to the extent those claims are asserted by AstraZeneca at trial and are found to be valid and enforceable. Defendants reserve all remaining counterclaims and defenses to the '247 patent.

4. This Stipulation is not an agreement as to the proper scope of an injunction, if any, or that Plaintiffs are entitled to an injunction against Defendants based on any agreements in this stipulation. For the avoidance of doubt, this stipulation alone does not entitle Plaintiffs to any injunctive relief, including an injunction pursuant to 35 U.S.C. § 271(e)(4)(A).

5. Nothing in this stipulation supersedes or supplants the safe harbor protections of 35 U.S.C. § 271(e)(1) or Defendants' ability to assert and rely on them.

6. Defendants and Plaintiffs specifically reserve the right to appeal any final judgment entered by this Court.

7. Should this Stipulation be vacated, nothing herein shall be construed as a waiver by Plaintiffs or Defendants of any claim or defense with the regard to the Federal Circuit Claims.

8. Defendants and Plaintiffs reserve all other claims and defenses.

Dated: March 29, 2022

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Respectfully submitted,

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IT IS SO ORDERED this 7th day of April, 2022.

A handwritten signature in black ink, reading "James M. Keelley". The signature is written in a cursive style with a large, stylized initial 'J'.

United States District Judge